K003994 APR 1 3 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact:

James A. Lee, Ph.D.
Regulatory Affairs Specialist

Device Identification:

Common Name:
Surgical ENT Shaver/ENT Drill

Trade Name: (optional)
KSEA UNIDRIVE II/II Plus and ENT Accessories

Indications: The KSEA Paranasal Sinus Shaver in conjunction with the UNIDRIVE II/II Plus control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to shave, debride, or cut tissue during ENT endoscopic surgical procedures. The KSEA Stammberger-Sachse Intranasal Drill/ENT Drill in conjunction with the UNIDRIVE II/II Plus control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to provide controlled cutting and removal of bone during ENT endoscopic surgical procedures.

Device Description: The UNIDRIVE II/II Plus system is a motorized, reusable surgical device system that can be used in conjunction with Paranasal Sinus Shaver, Stammberger-Sachse Intranasal Drill and ENT Drill.

Substantial Equivalence: The KSEA Paranasal Sinus Shaver, Stammberger-Sachse Intranasal Drill, and ENT Drill are substantially equivalent to the predicate devices since the basic features, design and intended uses are similar. The minor differences in design and dimensions between the KSEA Paranasal Sinus Shaver/ENT Drill and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of these devices.

Signed: _____
James A. Lee, Ph.D.
Regulatory Affairs Specialist

TABLE 1: SUBSTANTIAL EQUIVALENCE TABLE FOR ENT SHAVER BLADES AND CUTTERS FOR USE DURING ENT SURGICAL PROCEDURES

Manufacturer	Device	Basic Features	Speed (rpm)/ Modes	Blade Dimensions	Intended Use
KSEA	Paranasal Sinus Shaver	Handpiece with Suction Control Unit with Footswitch	333-3,000 Clockwise Counterclockwise Oscillate	Diameters: 2.0-4.0 mm Lengths: 7-12 cm	to shave, debride, or cut tissue during ENT endoscopic surgical procedures
KSEA (K953370)	ENT Shaver	Same	2,600 Clockwise Counterclockwise Oscillate	Diameters: Same Length: 8 cm	Same
Linvatec (K934379)	Apex Universal Drive System	Same	3,500-6,000 Clockwise Counterclockwise Oscillate	Diameter: 4.2 mm Length: 13 cm	Same

TABLE 2: SUBSTANTIAL EQUIVALENCE TABLE FOR DRILLS USED IN ENT SURGICAL PROCEDURES

Manufacturer	Device	Features	Bur Blades	Power Supply/ Speed	Intended Use
KSEA	ENT Drill	Straight or Angled Handpiece, Suction channel Footswitch	Diameters: 0.8-7.0 mm Length: 7.0 cm	Electric 1,000-40,000 rpm	To provide controlled cutting and removal of bone during ENT surgical procedures
Xomed-Treace (K90580)	Air Drill	Straight or Angled Handpiece, Footswitch	Diameters: 2.3-6.0 mm Lengths: 7.5-16 cm	Air 2,000-22,000 rpm	same
Xomed-Treace (K791407)	MPS Surgical Drill	Straight or Angled Handpiece, Irrigation Channel Footswitch	Unavailable	Electric Max: 48,000 rpm	same

TABLE 3: SUBSTANTIAL EQUIVALENCE TABLE FOR THE STAMMBERGER SACHSE INTRANASAL DRILL CONTROL FOR USE DURING ENDOSCOPIC SURGICAL PROCEDURES

KSEA Device	Basic Features	Control	Performance Specification
UNIDRIVE II/II Plus (Model:20711020/20711520)	power switch speed control footswitch switch for rotational direction connection ports for cables to footswitch and handpiece plus/minus buttons bar graph display and digital displays memory button	Hand Footswitch	Speed: 1,000-20,000 rpm Rotate clockwise and counterclockwise
Drill Engine (K950337) (Model: 250400 B)	power switch speed control pedal switches for rotational direction connection port for cable to handpiece	Footswitch	Maximum- 20,000 rpm Rotate clockwise and counterclockwise

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2001

James A. Lee, Ph.D.
Regulatory Affairs Specialist
Karl Storz Endoscopy- America, Inc.
600 Corporate Point Drive
Culver City, CA 90230

Re: K003994
Trade Name: UNIDRIVE II/II Plus System and ENT Accessories
Regulatory Class: II
CFR: 874.4250
Product Code: 77ERL
Dated: March 8, 2001
Received: March 23, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): Not yet assigned K003994

Device Name: UNIDRIVE II/II Plus System and ENT Accessories

Indications for Use: The KSEA Paranasal Sinus Shaver in conjunction with the UNIDRIVE II/II Plus control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to shave, debride, or cut tissue during ENT endoscopic surgical procedures.

Indications for Use: The KSEA Stammberger-Sachse Intranasal Drill or ENT Drill in conjunction with the UNIDRIVE II/II Plus control unit is a motorized, reusable surgical device system, intended for use by qualified surgeons to provide controlled cutting and removal of bone during ENT endoscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003994

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)